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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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COHEN, PONTANI, LIEBERMAN & PAVANE
551 FIFTH AVENUE
SUITE 1210
NEW YORK, NY 10176

EXAMINER

TYSON, MELANIE RUANO

ART UNIT PAPER NUMBER

3731

DATE MAILED: 05/11/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/811,555

Applicant(s)

WAGNER ET AL.

Examiner

Melanie Tyson

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 29 March 2004.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-11 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-11 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 06 July 2004 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☒ None of:
1. ☒ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date 29 March 2004.
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____.

DETAILED ACTION

Priority

1. Acknowledgment is made of applicant's claim for foreign priority based on an application filed in Europe on March 28, 2003. It is noted, however, that applicant has not filed a certified copy of the 03 007 084.1 application as required by 35 U.S.C. 119(b).

Specification

2. The disclosure is objected to because of the following informalities:

In line 13 of page 7, the tissue is referred to as reference number "18", but the tissue has been defined as reference number "14". Change reference number "18" to reference number --14--. Appropriate correction is required.

Claim Objections

3. Claims 2, 4, 9, and 11 are objected to because of the following informalities: The claims contain the word "preferably". Although those skilled in the art would understand what is claimed in light of the specification, the term "preferably" should be removed from claims 2, 4, 9, and 11 in order to improve clarity and precision of what is being claimed. Appropriate correction is required.

Claim Rejections - 35 USC § 112

4. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claim 1 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 1 recites the limitation "the distal end" in lines 2 and 3. There is insufficient antecedent basis for this limitation in the claim.

Claim Rejections - 35 USC § 102

5. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1-5, 7-9, and 11 are rejected under 35 U.S.C. 102(b) as being anticipated by Dubrul et al. (Patent No. 5,431,676).

Regarding claim 1, Dubrul et al. disclose a dilation pin (Figure 4, element 80) with a diameter that increases proximally from the distal end (78). Figure 1 shows a tubular guide sleeve (10), which has an inner diameter corresponding to the diameter of the distal end (78), since the distal end (78) is inserted through the tubular guide sleeve (10), reduced in diameter of the dilation pin (80), since the dilation pin is used to separate the guide sleeve (10), and which in its longitudinal direction may be separated over the entire length along at least one line (Figure 9). Regarding claim 2, Figure 9 shows a guide sleeve (10) comprising at least one break-off location (line extending through guide sleeve 10) extending in the longitudinal direction of the guide sleeve (10) over its whole length. Regarding claim 3, Figure 1 shows a veress cannula (40), which

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has an outer diameter corresponding to the inner diameter of the guide sleeve (10), since it passes through the guide sleeve (column 7, lines 27-29, 33-36, 41-42, and 52-55). Regarding claim 4, Figure 16 shows the guide sleeve (10) has two break-off locations (top and bottom) extending in the longitudinal direction of the guide sleeve (10), since it splits completely through both the top and bottom portions of the guide sleeve (10). Regarding claim 5, Dubrul et al. disclose the break-off locations are formed by perforation or a regionally weaker wall thickness (column 7, lines 17-19). Regarding claim 7, Figure 1 shows at least one holding element (32) is formed at the proximal end (not labeled) of the guide sleeve (10). Regarding claim 8, Figure 2 shows the guide sleeve (10) at its distal end (42) is formed tapered or conically, since it becomes progressively smaller towards one end. Regarding claim 9, Dubrul et al. disclose the guide sleeve (10) is manufactured of a transparent plastic (polyethylene, fluorinated ethylene propylene, etc.; column 7, lines 11-14). Regarding claim 11, Figure 9 shows at least one break-off location (line extending through guide sleeve 10) extending in the longitudinal direction of the guide sleeve (10) over its whole length.

Claim Rejections - 35 USC § 103

6. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

7. Claim 6 is rejected under 35 U.S.C. 103(a) as being unpatentable over Dubrul et al. in view of Hall et al. (Patent No. 6,939,327 B2).

Dubrul et al. disclose a dilation pin (Figure 4, element 80) with a diameter that increases proximally from the distal end (78). Figure 1 shows a tubular guide sleeve (10), which has an inner diameter corresponding to the diameter of the distal end (78), since the distal end (78) is inserted through the tubular guide sleeve (10), reduced in diameter of the dilation pin (80), since the dilation pin is used to separate the guide sleeve (10), and which in its longitudinal direction may be separated over the entire length along at least one line (Figure 9). Dubrul et al. does not disclose that the guide sleeve (10) is formed by at least two sleeves. Hall et al. teach a guide sleeve (Figure 3b, element 82) formed by at least two sleeves (84 and 92). Figure 3b further shows that the two sleeves (84 and 92) are separate from each other, arranged in one another (column 2, lines 42-43), and in each case comprise a correspondingly extending break-off location (100 and 102), wherein the break-off locations (100 and 102) in the two sleeves (84 and 92) are arranged circumferentially displaced to one another (column 8, lines 34-38). This dual sheath configuration improves kink resistance (column 8, lines

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40-43). Therefore, to construct the guide sleeve of Dubrul et al. with at least two sleeves would have been obvious to one of ordinary skill in the art at the time the invention was made in order to reduce susceptibility to kinking during use.

8. Claim 10 is rejected under 35 U.S.C. 103(a) as being unpatentable over Dubrul et al. in view of Osypka (Patent No. 4,687,469).

Dubrul et al. disclose a dilation pin (Figure 4, element 80) with a diameter that increases proximally from the distal end (78). Figure 1 shows a tubular guide sleeve (10), which has an inner diameter corresponding to the diameter of the distal end (78), since the distal end (78) is inserted through the tubular guide sleeve (10), reduced in diameter of the dilation pin (80), since the dilation pin is used to separate the guide sleeve (10), and which in its longitudinal direction may be separated over the entire length along at least one line (Figure 9). Dubrul et al. does not disclose the dilation pin (80) comprises at least one cutter for separating the guide sleeve (10). Osypka teaches using a severing device (Figure 11, element 7) comprising a cutter (9) in order to sever a guide sleeve (Figure 12, element 6) that is not formed with a slit or with one or more longitudinally extending weakened portions (column 6, line 64 through column 7, line 6). Therefore, to construct the dilation pin of Dubrul et al. with at least one cutter would have been obvious to one of ordinary skill in the art at the time the invention was made in order to facilitate separating a guide sleeve that is not formed with a slit or with one or more longitudinally extending weakened portions.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Melanie Tyson whose telephone number is (571) 272-9062. The examiner can normally be reached on Monday through Friday 7:30 a.m. - 5:00 p.m. EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Anhtuan Nguyen can be reached on (571) 272-4963. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Melanie Tyson *MT*
May 2, 2006


ANH TUAN T. NGUYEN
SUPERVISORY PATENT EXAMINER

5/4/06.